K120479 510(k) SUMMARY

(Per 21 CFR 807.92)

NOV 8 2012

General Company Information

Name:	Musculoskeletal Transplant Foundation
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Date Prepared

November 5, 2012

General Device Information

Product Name:	MTF Fascia
Classification:	Surgical Mesh 21 CFR §878.3300 – Product codes: OWY, OWW Class II

Predicate Devices

OrthADAPT® PR
Pegasus Biologics, Inc
510(k) K090288

Synthasome X-Repair
Synthasome, Inc.
510(k) K083307

Description

MTF Fascia is dehydrated, decellularized human allograft fascia minimally processed to preserve the extracellular matrix of the fascia. The fascia is reinforced with a resorbable Poly-L-Lactic Acid (PLLA) fiber woven into the fascia to enhance suture retention of the fascia. MTF Fascia is aseptically processed—no terminal sterilization is conducted. The device passes USP sterility testing and satisfies FDA requirements for LAL endotoxin limit for medical devices. The device must be rehydrated prior to use following the procedures described in the Instructions for Use.

Intended Use (Indications)

MTF Fascia is intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. It is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair. MTF Fascia is for single patient use only.

Substantial Equivalence

This submission supports the position that the MTF Fascia is substantially equivalent to two previously cleared devices:

OrthADAPT® PR – Pegasus Biologics, Inc. [K090288]
Synthasome X-Repair – Synthasome, Inc. [K083307]

MTF Fascia is substantially equivalent to Synthasome X-Repair in material and biomechanical and histologic outcomes obtained from both clinical (cadaver) and preclinical in vivo models. MTF Fascia is substantially equivalent to OrthADAPT PR in indication for use, and both devices are composed of a collagen matrix reinforced with a polymer component.

The clinical (cadaver) and preclinical tests demonstrated the biocompatibility and substantial equivalence of MTF Fascia in comparison to its predicate devices:

- ISO 10993 testing of the PLLA fiber
- Cytotoxicity Study Using the ISO Elution Method
- Risk Analysis for MTF Fascia
- Established history of using the material components of the device
- Published literature
- Animal studies were included in this 510(k) submission to serve as subchronic toxicity tests for MTF Fascia. In addition, a cytotoxicity study has demonstrated that MTF Fascia is not cytotoxic.
- Data presented in peer-reviewed journals and submitted within this 510(k) supported a finding of substantial equivalencies between MTF Fascia and Synthasome X-Repair.

The MTF Fascia has been demonstrated to be substantially equivalent to its predicate devices.

Safety Information

MTF Fascia is single-donor processed. This device was not subjected to terminal sterilization. MTF Fascia is aseptically processed and passes USP <71> Sterility Tests. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, And Cellular and Tissue Based Products, as applicable.

Conclusion

Musculoskeletal Transplant Foundation believes that the information provided in this 510(k) submission establishes that similar legally marketed devices have been used for the same clinical applications as MTF Fascia. The materials from which MTF Fascia is fabricated have an established history of use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Musculoskeletal Transplant Foundation
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Ms. Nancy Joy
Senior Regulatory Affairs Submission Specialist
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004-5794

November 8. 2012

Re: K120479
Trade/Device Name: MTF Fascia
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OWY, OWW
Dated: September 27, 2012
Received: September 28, 2012

Dear Ms. Joy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. INDICATIONS FOR USE

510(k) Number (if known): not known

Device Name: MTF Fascia

Indications for Use:

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MTF Fascia is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

MTF Fascia is for single patient use only.

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120479